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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,767	03/24/2004	Sean S. Suh	001227/0125	7927
69095 7590 02/11/2009 STROOCK & STROOCK & LAVAN, LLP 180 MAIDEN LANE NEW YORK, NY 10038				
EXAMINER HARVEY, JULIANNA NANCY				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,767

Applicant(s)

SUH ET AL.

Examiner

Julianna N. Harvey

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 20-31, 34-38 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 10, 20-24 and 34-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-9, 11-17, 25-31 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 December 2008 has been entered.

Claim Objections

Claims 29 and 30 are objected to because of the following informalities: "locking clip engaging portion" should be replaced with "locking clip expanding portion" to maintain consistency with claim 28. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 9, 11, 12, 25, 26, 43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryant et al. (US 5,649,931 A). Regarding **claim 1**, Bryant et al.

disclose a bone fastener implantation and removal system comprising: a bone plate (col. 2, lines 39-45) including a top surface, a bottom surface, and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of fasteners ("12") *receivable within the fastener holes formed in the bone plate*; and a tool including: a drive shaft ("14" and "16") having proximal and distal ends, an intermediate portion, an outer sleeve engaging portion ("38"), and a length; a handle portion ("20" and "32") associated with the drive shaft proximal end; a fastener engaging portion associated with the drive shaft distal end, the fastener engaging portion comprising a first surface ("34") *configured to axially engage one of the plurality of fasteners* and a second surface ("30") *configured to rotationally engage the fastener*; and an outer sleeve ("18") associated with the drive shaft intermediate portion, the sleeve comprising a proximal end, a distal end, and a drive shaft engaging portion ("36"), the distal end *contacting the top surface of the bone plate to facilitate removal of the fasteners from the fastener holes; wherein the outer sleeve engaging portion and the drive shaft engaging portion are configured to coact to allow at least a portion of the drive shaft to translate linearly within the sleeve* (Figs. 4-5). Regarding **claim 2**, Bryant et al. disclose that the drive shaft comprises a cannulated fastener driving portion ("14") and an inner shaft portion ("16"), at least a portion of the inner shaft portion being slidably disposed within the fastener driving portion ("55"), the inner shaft portion *being configured to axially engage the fastener while the fastener driving portion is configured to rotationally engage the fastener* (Figs. 4-5). Regarding **claim 8**, Bryant et al. disclose that the first surface comprises at least one radial member (col. 3, lines 9-11) *configured to axially engage a*

recess in a head of the fastener. Regarding **claim 9**, Bryant et al. disclose that the first surface comprises a plurality of radial members (col. 3, lines 9-11), *each of which is configured to axially engage corresponding recesses in the fastener head.* Regarding **claim 11**, Bryant et al. disclose that the sleeve engaging portion and drive shaft engaging portions comprise complementary threads (col. 3, lines 17-19). Regarding **claim 12**, Bryant et al. disclose an inner shaft ("16") having a fastener engaging surface ("34") at one end, the drive shaft further comprising a cannulation ("14") *configured and sized to accept at least a portion of the inner shaft, wherein when the inner shaft is disposed within the cannulation, the fastener engaging surface extends distally beyond the distal end of the drive shaft ("55")* (Figs. 4-5). Regarding **claim 25**, Bryant et al. disclose a bone fastener implantation and removal system comprising: a bone plate (col. 2, lines 39-45) including a top surface, a bottom surface, and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of fasteners ("12") *receivable within the fastener holes formed in the bone plate*; and a tool including: a drive shaft ("14" and "16") having a fastener engaging end and a sleeve engaging portion ("38"), the fastener engaging end comprising a rotational engagement portion ("30") and an axial engagement portion ("34"); a sleeve ("18") disposed about at least a portion of the drive shaft, the sleeve comprising a proximal end, a distal end, and a drive shaft engaging portion ("36"), the distal end *contacting the top surface of the bone plate to facilitate removal of one of the plurality of fasteners from the fastener holes*, wherein the sleeve engaging portion and the drive shaft engaging portion comprise complementary threads (col. 3, lines 17-19) *configured to allow the drive shaft to*

translate linearly within the sleeve when the drive shaft is rotated relative to the sleeve (Figs. 4-5). Regarding **claim 26**, Bryant et al. disclose that the drive shaft comprises a cannulated fastener driving portion ("14") and an inner shaft portion ("16"), at least a portion of the inner shaft being slidably disposed ("55") within the driving portion, *the inner shaft portion being configured to axially engage one of the fasteners while the driving portion is configured to rotationally engage the fastener* (Figs. 4-5). Regarding **claim 43**, Bryant et al. disclose a bone fastener implantation and removal system comprising: a bone plate (col. 2, lines 39-45) including a top surface, a bottom surface, and a plurality of fastener holes extending from the top surface to the bottom surface; a plurality of bone fasteners ("12") *receivable within the fastener holes formed in the bone plate*; and a tool including: an inner shaft ("16") *for engaging one of the bone fasteners*, an outer shaft ("14") *for engaging the bone fastener*, and an outer sleeve ("18") *for contacting the top surface of the bone plate*; wherein the inner shaft is configured to *axially engage ("34") the bone fastener* and is slidably disposed ("55") within the outer shaft; wherein the outer shaft is configured to *rotationally engage ("30") the bone fastener* and further comprises an outer sleeve engaging portion ("38"); and wherein the outer sleeve further comprises an outer shaft engaging portion ("36") *such that the outer shaft may translate linearly within the outer sleeve when the outer sleeve engaging portion rotationally engages the outer shaft engaging portion* (Figs. 4-5). Regarding **claim 45**, Bryant et al. disclose that the outer sleeve engaging portion and the outer shaft engaging portion comprise complementary threads ("36" and "38") (Figs. 4-5).

The text italicized above corresponds to statements of intended use or other functional statements. These statements do not impose any structural limitations on the claims distinguishable over Bryant et al., which is capable of being used as claimed if one so desires. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). In addition, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. (US 5,649,931 A). Bryant et al. disclose that the cannulated fastener driving portion *is configured to slidably receive the inner shaft ("55")* (Figs. 4-5). Bryant et al. fail to disclose that the inner shaft portion is tapered. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was

made to construct inner shaft of Bryant et al. such that it is tapered, since Applicant has not disclosed that such solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing an inner shaft that is slidably received in the fastener driving portion. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. (US 5,649,931 A) in view of Frigg et al. (US 2003/0036758 A1). Bryant et al. discloses the claimed invention except that the axial fastener-engagement portion comprises a thread. However, Bryant et al. disclose that the recess in the head of the fastener is hexagonal and the axial fastener-engagement portion is complementary to the recess (col. 3, lines 9-11). Frigg et al. teach that the recess in the head of a fastener can be a hexagonal recess or an internally threaded recess to receive a complementary driving tool (para. 0033). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bryant et al. such that the recess in the head of the fastener and the axial fastener-engagement portion are threaded, as suggested by Frigg et al., as doing so is merely a simple substitution of one known element for another to obtain predictable results.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. (US 5,649,931 A) in view of Burke (US 5,431,660 A). Bryant et al. disclose the claimed invention except that at least a portion of the sleeve has a roughened outer surface. Burke teaches a bone fastener implantation and removal tool comprising an outer sleeve ("84" and "86") that can linearly translate with respect to a drive shaft ("70")

wherein the outer sleeve is provided with a roughened outer surface to allow the user to better grasp the outer sleeve (col. 7, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the outer sleeve of Bryant et al. with a roughened outer surface, as suggested by Burke, as doing so allows the user to better grasp the outer sleeve.

Claims 14-17, 28-31, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. (US 5,649,931 A) in view of Bailey et al. (US 2002/0151899 A1). Regarding **claim 14**, Bryant et al. disclose that the fastener engaging portion further comprises a locking clip expanding portion ("30") and that the locking clip expanding portion *is configured to expand the locking clip* (Figs. 4-5). Regarding **claim 15**, Bryant et al. disclose that the locking clip expanding portion *is configured to expand the locking clip to a dimension greater than an outer dimension of the fastener head*. Regarding **claim 16**, Bryant et al. disclose that the locking clip expanding portion *is configured to expand the locking clip to a dimension smaller than an outer diameter of the fastener head*. Regarding **claim 28**, Bryant et al. disclose that the fastener engaging end further comprises a locking clip expanding portion ("30"), the fastener engaging end of the drive shaft *configured to engage one of the plurality of fasteners disposed within one of the plurality of fastener holes formed in the plate*, and that the fastener engaging end *is configured to expand the locking clip when the drive shaft engages the fastener* (Figs. 4-5). Regarding **claim 29**, Bryant et al. disclose that the locking clip expanding portion *is configured to expand the locking clip to a dimension greater than an outer dimension of the fastener head*. Regarding **claim 30**,

Bryant et al. disclose that the locking clip expanding portion *is configured to expand the locking clip to a dimension smaller than an outer diameter of the fastener head.*

Regarding **claim 44**, Bryant et al. disclose that the outer shaft includes a fastener engaging end ("30") *for rotationally engaging the bone fastener* and that the fastener engaging end *is configured to expand the fastener locking clip when the outer shaft engages one of the plurality of fasteners* (Figs. 4-5). Bryant et al. fail to disclose that the fastener is disposed within the fastener holes formed in the plate, that the fastener hole is provided with an expandable locking clip *configured to engage a portion of the fastener to prevent the fastener from being backed out of the fastener hole (claim 14)*, that at least a portion of the fastener *is configured to expand the locking clip to a dimension substantially equal to the outer diameter of the fastener head when the tool is engaged with the fastener and the tool is operated to remove the fastener from the bone plate (claim 17)*, that the plate has an expandable locking clip disposed within the fastener hole, the clip *configured to engage a portion of the fastener to prevent the fastener from backing out of the fastener hole (claim 28)*, that *when the tool is engaged with the fastener and the tool is operated to remove the fastener from the bone plate, an axial removal force applied by the tool is greater than a fastener locking force of the locking clip (claim 31)*, that the bone fastener is disposed within one of the plurality of fastener holes formed in the plate, and that the plate has an expandable locking clip disposed within the fastener hole, the clip *configured to engage a portion of one of the plurality of fasteners to prevent one of the plurality of fasteners from backing out of the one of the plurality of fastener holes (claim 44)*. Bailey et al. teach a bone plate ("12")

and a plurality of fasteners ("14") disposed within fastener holes in the plate (Fig. 4). Bailey et al. also teach a locking clip ("16") disposed within each of the fastener holes to prevent the fasteners from backing out of the plate (Fig. 4; para. 0032). Bailey et al. also teach a tool ("90") configured to remove the fastener from the plate (Fig. 10). As such, the axial removal force applied by the tool must be greater than the fastener locking force of the clip in order to successfully remove the fastener. Furthermore, at least a portion of the fastener is configured to expand the locking clip to a dimension substantially equal to the outer diameter of the fastener head when the removal tool is operated to remove the fastener (Fig. 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Bryant et al. plate with locking clips that engage the fasteners when they are disposed within the fastener holes (**claims 14, 28, and 44**), as suggested by Bailey et al., as doing so prevents backout of the fastener. It would have been further obvious that a portion of the fastener must be configured to expand the locking clip to a dimension substantially equal to the outer diameter of the fastener head when the tool is engaged with the fastener and the tool is operated to remove the fastener from the bone plate (**claim 17**), as shown by Fig. 10 of Bailey et al., as the locking clip must stay expanded to a diameter substantially equal to that of the fastener to allow complete removal of the fastener. As stated above, the axial removal force applied by the tool must be greater than the fastener locking force of the clip in order to successfully remove the fastener (**claim 31**).

Response to Arguments

Applicant's arguments with respect to claims 1, 25, and 43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., until 2:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733